

Notice of Allowability

Application No.

10/775,180

Examiner

Karen Cochrane Carlson, Ph.D.

Applicant(s)

ROSEN ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/31/2006.
2. ☒ The allowed claim(s) is/are 26 and 33-77.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12/05A-D; 3/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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This Notice of Allowability is in response to the election filed March 31, 2006.

Applicant's election with traverse of Group 5 (Inventions 645-805) drawn to a method of treating obesity via albumin fusion No. 137 in Table 2 in the reply filed on March 31, 2006 is acknowledged. The traversal is on the ground(s) that a species requirement based on the specific constructs listed in Table 2 is improper, and that the examination of fusion constructs comprising albumin and GLP-1 polypeptides would not propose a serious search burden on the Examiner. This is not found persuasive because, regarding the species election, no species election was set forth for Applicants, but rather a specific sequence would be searched. Upon search of Fusion No. 137, and extensive database searching, the Examiner did not find art on tandem GLP-1 sequences fused to albumin. Therefore, the Examiner has rejoined the breadth of Claim 26 as amended, and new Claims 33-77 in the examination.

The requirement is still deemed proper and is therefore made FINAL.

The Office is in receipt of the Reply To Requirement for Information under 37 CFR 1.105 filed March 31, 2006. The Examiner appreciates Applicant's representative pointing out references relevant to the instant invention for a method of treating obesity or reducing weight using fusion proteins comprising tandem GLP-1 polypeptides and albumin. These references have been initialed on the five submitted IDS PTO-1449s, while those references not relevant to the invention have been lined through.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Kenley Hoover on May 2, 2006.

Examiner's Amendments to the Claims:

Please cancel non-elected Claims 1, 14-16, 29, and 30.

The following is an **Examiner's Statement of Reasons for Allowance**: The prior art of record does not teach or suggest a method for treating obesity or losing weight by administering a fusion protein comprising tandem GLP-1 polypeptides and albumin. A search of the sequence for Construct ID 3070 having SEQ ID NO: 447 and also SEQ ID NO: 449 did not produce art against the instantly claimed invention. Also, a search of the databases revealed fusion proteins comprising single GLP-1 polypeptides fused to albumin, but not tandem GLP-1 polypeptides fused to albumin – see US 2004/0053370, for example, and "albugon" as taught by Baggio et al. (2004. A Recombinant Human Glucagon-Like Peptide (GLP)-1-Albumin Protein (Albugon) Mimics Peptidergic Activation of GLP-1 Receptor-Dependent Pathways Coupled With Satiety, Gastrointestinal Motility, and Glucose Homeostasis. Diabetes. 53(9): 2492-2500). Thus, while the specific sequences/constructs set forth in Claim 45 were not searched, the combination of search for Construct ID 3070 and word search in the databases which produced art around the invention and should have produced art against the invention if the invention were in the databases, these sequences and constructs are novel. Therefore, the claims are allowable over the art of record.

Additionally, GLP-1 activity is specifically defined in Table 1 at page 23-24 in the second column identified as "Biological Activity", and the Deposit under the Budapest Treaty is found in Table 3 and paragraph [0076]. There are many applications for patent by Applicants regarding albumin fusion proteins. However, perusal of these applications did not result in finding claims under examination that would warrant double patenting rejections.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946.

The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Karen Cochrane Carlson Ph.D." with a stylized flourish at the end.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER